PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference SUSA-12037	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/US2007/087425	International filing date *(day/month/year)* 13 December 2007 (13.12.2007)	Priority date *(day/month/year)* 13 December 2006 (13.12.2006)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant SUSAVION BIOSCIENCES, INC.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- ☒ Box No. I — Basis of the report
- ☐ Box No. II — Priority
- ☐ Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV — Lack of unity of invention
- ☒ Box No. V — Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI — Certain documents cited
- ☐ Box No. VII — Certain defects in the international application
- ☒ Box No. VIII — Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 16 June 2009 (16.06.2009)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Beate Giffo-Schmitt e-mail: pt03.pct@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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18 E. UNIVERSITY DRIVE
SUITE 101
MESA, AZ 85201

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing (*day/month/year*)	05 AUG 2008
Applicant's or agent's file reference SUSA-12037	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/US07/87425	13 December 2007 (13.12.2007)	13 December 2006 (13.12.2006)

International Patent Classification (IPC) or both national classification and IPC

IPC: **A61K 38/07**(2006.01),**38/08**(2006.01);**C07K 5/10**(2006.01),**7/06**(2006.01)
USPC: 514/16,17,18;530/328,329,330

Applicant

SUSAVION BIOSCIENCES, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I — Basis of the opinion
- ☐ Box No. II — Priority
- ☐ Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV — Lack of unity of invention
- ☒ Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI — Certain documents cited
- ☐ Box No. VII — Certain defects in the international application
- ☒ Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis(b)* that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	09 July 2008 (09.07.2008)	Valerie Bell-Harris Jeffrey H. Russel Telephone No. (571) 272-1600

Form PCT/ISA/237 (cover sheet) (April 2007)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US07/87425

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

☒ the international application in the language in which it was filed

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

a. type of material

☒ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☒ on paper

☒ in electronic form

c. time of filing/furnishing

☒ contained in the international application as filed.

☒ filed together with the international application in electronic form.

☐ furnished subsequently to this Authority for the purposes of search.

4. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
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Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims NONE	YES
	Claims 1-25	NO
Inventive step (IS)	Claims NONE	YES
	Claims 1-25	NO
Industrial applicability (IA)	Claims 1-25	YES
	Claims NONE	NO

2. Citations and explanations:

Please See Continuation Sheet

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US07/87425

Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

V. 2. Citations and Explanations:
Claims 1, 4-14, and 16-25 lack novelty under PCT Article 33(2) as being anticipated by Secombes et al. Secombes et al teach peptides of SEQ ID NOS:12, 14, 16, 18, and 19, in which the G residue at positions 3, 4, or 5 corresponds to Applicant's G in the second-listed core sequence; and the S residue at position 6 corresponds to Applicant's S in the second-listed core sequence. The peptides are antimicrobial and immunostimulatory, and are administered by injection, topically, or orally. See, e.g., paragraphs [0001], [0102], [0106], and [0107], and claims 1-20 and 49-52. With respect to instant claims 6-9, the Arg residue including its side chain at position 1 of SEQ ID NOS:12, 14, 16, 18, and 19 of Secombes et al can correspond to Applicant's branched construct. Note that the claims do not impose any limitations on the chemical nature of the construct, and do not require multiple therapeutic peptides to be present in a branched relationship to one another. In view of the similarity in peptide structure and method steps between Secombes et al and Applicant's claimed method, inherently the production of at least one therapeutically beneficial cytokine, and the activity of at least one pathogen-directed antibody will be stimulated in Secombes et al to the same extent claimed by Applicant. With respect to instant claims 21-25, Secombes et al teach the only positive process step recited in the claims, i.e. contacting a test sample with a composition according to claim 5. Accordingly, the claims are anticipated by Secombes et al, and the intended use limitations do not impart novelty to the claims.

Claims 1, 2, 4-15, and 18-25 lack novelty under PCT Article 33(2) as being anticipated by D. Livant. D. Livant teaches a polylysine dendrimer to which is attached a peptide comprising the amino acid sequence PHSCN. The P at position 1 of the peptide of D. Livant corresponds to the P residue in Applicant's first-listed core sequence; the S residue at position 3 corresponds to the S residue in Applicant's first-listed core sequence; and Applicant's m=0; n=1; and p=2. The compositions of D. Livant are used to treat cancer in a patient. See, e.g., claims 1-18. With respect to instant claims 4 and 5, to the extent that "immunostimulatory" is an intended use limitation, such a limitation does not impart novelty to product claims which are otherwise anticipated by the prior art. Alternatively, in view of the similarity in structure between D. Livant's composition and Applicant's claimed peptide, inherently the former will be immunostimulatory to the same extent claimed by Applicant. With respect to instant claims 12 and 18-20, in view of the similarity in peptide structure and method steps between D. Livant and Applicant's claimed method, inherently the production of at least one therapeutically beneficial cytokine, and the activity of at least one pathogen-directed antibody, will be stimulated in D. Livant to the same extent claimed by Applicant. With respect to instant claims 21-25, D. Livant teaches the only positive process step recited in the claims, i.e. contacting a test sample with a composition according to claim 5. Accordingly, the claims are anticipated by D. Livant, and the intended use limitations do not impart novelty to the claims.

Claims 1-9 lack novelty under PCT Article 33(2) as being anticipated by Sarig et al. Sarig et al teach peptide II, i.e. KXFVGGLS (see

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

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Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

Figure 1). This peptide comprises Applicant's SEQ ID NO:1, electronic form. With respect to instant claims 4 and 5, to the extent that "immunostimulatory" is an intended use limitation, such a limitation does not impart novelty to product claims which are otherwise anticipated by the prior art. Alternatively, in view of the similarity in structure between Sarig et al's peptide and Applicant's claimed peptides, inherently the former will be immunostimulatory to the same extent claimed by Applicant. With respect to instant claims 6-9, the Lys residue including its side chain at position 1 of the peptide of Sarig et al can correspond to Applicant's branched construct. Note that the claims do not impose any limitations on the identity of the construct, and do not require multiple therapeutic peptides to be present in a branched relationship to one another.

Claims 1-25 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry. The claimed invention would have been expected to have industrial applicability in the therapeutic treatment of infections, cell proliferative diseases, and immunosuppressive disorders.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 1-25 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims are indefinite for the following reason(s): It is unclear to what "thereof" at claim 1, line 10, refers. If "thereof" refers to the therapeutic peptide of claim 1, then the claimed peptides embrace peptides comprising fewer than four amino acids. If "thereof" refers to the core sequences, then the claimed peptides embrace peptides which do not include all of the amino acids required by the core sequences. SEQ ID NO:1 is defined in the electronic form of the sequence listing as VGGLS, which contradicts SEQ ID NO:1 as set forth in claim 3. It is not clear which amino acid sequence was intended to be claimed.